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| 10/716,982 | 11/19/2003 | Binic V. Lipps | FWLPAT019US | 6836 |
| 43737 | 7590 | 04/14/2008 | EXAMINER | |
| John R. Casperson P.O. Box 36369 Pensacola, FL 32516-6369 | | | REDDIG, PETER J | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/716,982

Applicant(s)

LIPPS ET AL.

Examiner

PETER J. REDDIG

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 January 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,8-12,16-18,20 and 24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,8-12,16-18,20 and 24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/888)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. The Amendment filed January 31, 2008 in response to the Office Action of August 23, 2007 is acknowledged and has been entered. Previously pending claims 4-7, 13-15, 19, and 21-23 have been cancelled, claims 1-3, 8-12, 16-18, and 20 have been amended and new claim 24 has been added.

2. Claims 1-3, 8-12, 16-18, 20 and 24 are currently being examined.

New Grounds of Rejection
Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 18 and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claim 18 recites the limitation "the plurality of proteomic cancer markers from different types of cancer cells " in claim 20. There is insufficient antecedent basis for this limitation in the claim as claim 20 does not recite "the plurality of proteomic cancer markers from different types of cancer cells ".

5. Claim 24 recites the limitation "the plurality of proteomic cancer markers from different types of cancer cells " in claim 20. There is insufficient antecedent basis for this limitation in the claim as claim 20 does not recite "the plurality of proteomic cancer markers from different types of cancer cells ".

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-3, 8-12, 16-18, 20 and 24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors to be considered in determining whether undue experimentation is required are summarized in *re Wands* 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir, 1988). The court in *Wands* states: "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (*Wands*, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The claims are drawn to a non-invasive cancer screening method comprising a) providing a mixture of proteomic cancer markers from different types of cancer cells, said mixture containing proteomic cancer markers identified and markers not yet identified; b) forming polyclonal antibodies against the mixture; c) forming a reagent from said polyclonal antibodies; d) obtaining a saliva sample from a human not diagnosed with cancer; e) bringing said saliva sample together with the reagent to form an assay sample, and f) assaying the sample

by simple ELISA to determine whether an immunological reaction has occurred in the assay sample. wherein ELISA test results higher than a predetermined value are indicative of a positive screening test for cancer OR a non-invasive cancer screening method comprising a) providing a mixture of proteomic cancer obtained from breast, liver, colon, and ovarian cancers, said mixture containing proteomic cancer markers identified and markers not yet identified; b) forming polyclonal antibodies against the mixture; c) forming a reagent from said polyclonal antibodies; d) obtaining a saliva sample from a human not diagnosed with cancer; e) forming a saliva sample from the specimen f) bringing said saliva sample together with the reagent to form an assay sample, and g) assaying the sample by simple ELISA titer test to determine whether an immunological reaction has occurred in the assay sample, wherein ELISA test results of greater than 1:1000 are indicative of a positive screening tests.

The specification teaches that lysates from four cells lines, HT-29/breast cancer, Diji/colon cancer, CCL-13/liver cancer, and Sk-ov-3/ ovarian cancer or a mixture of lysates, denoted proteomic cancer markers (PCM), from all four cell lines was used to make polyclonal antibodies, see p. 7-8. The specification teaches that the proteomic cancer markers were immunogenic, see p. 9 and Table 1. The specification teaches that using the polyclonal antibodies to the mixture of cell lysates from the four cancer cells most saliva specimens from normal individuals had a titer less than 1000, see p 9 and 10 and table 2. The specification teaches that titers above 1:1000 were tentatively considered positive for early diagnosis of cancer, see p. 10, lines 12-13. The specification teaches that saliva samples from normal individuals with titers greater than 1:1000 were also reactive with polyclonal antibodies produced to the individual cancers, see p. 11 and table 3. The specification teaches that

polyclonal antibodies against the mixture of cancer lysates produced titers of 1800 to 3600 when saliva samples from stomach, lung and breast cancer patients were used and a titer of 450 in saliva samples from a post-treatment prostate/vocal cancer patient, see p. 12 and Table 4. The specification teaches that the PCMs in the prostate/vocal cancer patient should have been higher and suggests that treatment brought the level of PCMs down.

One cannot extrapolate the teachings of the specification to the enablement of the claims because the specification gives insufficient guidance and direction as to what predetermined value in the ELISA test is indicative of a positive screening test for cancer. The specification appears to arbitrarily choose a titer of 1:1000 as a cutoff for a positive test, see p. 10. The specification then tests saliva samples from normal individuals with a titer greater than 1:1000 against the individual PCM antibodies and finds reactivity with the individual PCM polyclonal antibodies, see p. 11 and Table 3. However, there is no evidence presented that these individuals with the titers greater than 1000 actually have cancer and, thus, these high titers could be present in the absence of cancer. Additionally, in the prostate/vocal cancer patient with the low PCM titer it is unclear as to when the sample was taken and whether the patient was cancer free at the time and, thus, this low titer could be occurring in the presence of cancer. Thus, the only predetermined value taught in the specification a titer of 1:1000 is not predictably useful for indicating a positive test for cancer as the claimed method gives values above 1:1000 in individuals that are apparently normal and also produces values below 1:1000 in individuals who appear to have cancer. Given that Boyd (The Basic Science of Oncology, 1992, McGraw-Hill, Inc., p.379) teaches that diagnostic tests are used to distinguish patients with and without a particular disease, see p.379, right column, one of skill in the art could not predictably use the

claimed method without undue experimentation as the only predetermined value taught in the specification as indicative of cancer does not predictably indicate a positive screening test for cancer.

Furthermore, Stites et al (Medical Immunology, 9th Ed, Appleton and Lange, 1997, page 250-251) teaches the importance of cut-off points in diagnostic tests. Although the claims are drawn to screening, given that the positive screening test is determined by an ELISA test higher than a predetermined value, the teachings of Stites are relevant to the claimed methods. Stites et al specifically teaches that when any diagnostic test is used to make a decision, there is some probability of drawing an erroneous conclusion and that predictive value theory can be used to deal with this problem. The reference further teaches that diagnostic sensitivity is defined as the fraction of diseased subjects with abnormal test results and that diagnostic specificity is defined as the fraction of nondiseased subjects who have a normal laboratory test. Further, Stites et al teach that the positive predictive value is the fraction of abnormal tests that represent disease and the negative predictive value is the fraction of normal tests that represent the absence of disease (p. 251, col. 1). Stites et al specifically teach that diagnostic sensitivity and specificity reveal something about the test *given prior knowledge about the disease status* (emphasis in the original document), whereas positive and negative predictive values *estimate the likelihood of disease given the test result* (emphasis in the original document). Clearly it is the latter case that is of interest when trying to make a diagnosis (p. 251, col. 2). The difficulty with the determination of the positive predictive value for the claimed method, is that neither the claims nor the specification provide sufficient guidance on how to determine the positive predictive value for a positive screening test for cancer. Given that the only predetermined value taught in the

specification (a titer of 1:1000) and claimed as indicative of cancer does not predictably indicate a positive screening test for cancer, as it cannot be determined from the teachings of the specification if individuals with titers above 1000 are positive for cancer or if individuals below 1000 are negative for cancer. Thus one of ordinary skill in the art could not predictably use the method as claimed without undue experimentation in the absence of further guidance and direction.

Additionally, even if an appropriate cutoff value were to be identified, one of skill in the art would not predictably expect that the broadly claimed mixture of cancer cells methods would work using all cancer cells, which is inclusive of cancer cell lines, which do not predictably express the same protein produced by tumors *in vivo* because of the artifactual nature of cultured cells.

In particular the characteristics of cultured cell lines generally differ significantly from the characteristics of the primary tumor. As discussed in Freshney (Culture of Animal Cells, A Manual of Basic Technique, Alan R. Liss, Inc., 1983, New York, p. 4), it is recognized in the art that there are many differences between cultured cells and their counterparts *in vivo*. These differences stem from the dissociation of cells from a three-dimensional geometry and their propagation on a two-dimensional substrate. Specific cell interactions characteristic of histology of the tissue are lost. The culture environment lacks the input of the nervous and endocrine systems involved in homeostatic regulation *in vivo*. Without this control, cellular metabolism may be more constant *in vitro* but may not be truly representative of the tissue from which the cells were derived. This has often led to tissue culture being regarded in a rather skeptical light (p. 4, see Major Differences *In Vitro*). Further, Dermer (Bio/Technology, 1994, 12:320) teaches

that, a petri dish cancer is a poor representation of malignancy, with characteristics profoundly different from the human disease. Dermer further teaches that when a normal or malignant cell adapts to immortal life in culture, it takes an evolutionary-type step that enables the new line to thrive in its artificial environment and thus transforms a cell from one that is stable and differentiated to one that is not. The reference states that evidence of the contradictions between life on the bottom of a lab dish and in the body has been in the scientific literature for more than 30 years. Clearly it is well known in the art that cells in culture exhibit characteristics different from those *in vivo* and cannot duplicate the complex conditions of the *in vivo* environment involved in host-tumor and cell-cell interactions. Further, the art recognizes the problem of molecular artifacts associated with cell culture. For example, Drexler et al (Leukemia and Lymphoma, 1993, 9:1-25) specifically teach, in the study of Hodgkin and Reed-Sternberg cancer cells in culture, that the acquisition or loss of certain properties during adaptation to culture systems cannot be excluded. This is exemplified by the teachings of Zellner et al (Clin. Can. Res., 1998, 4:1797-1802) who specifically teach that products are overexpressed in glioblastoma (GBM)-derived cell lines which are not overexpressed *in vivo*. Drexler et al further teach that only a few cell lines containing cells that resemble the *in-vivo* cancer cells have been established and even for the *bona fide* cancer cell lines it is difficult to prove that the immortalized cells originated from a specific cancer cell (see attached abstract). Further, Embleton et al (Immunol Ser, 1984, 23:181-207) specifically teaches that in procedures for the diagnosis of osteogenic sarcoma, caution must be used when interpreting results obtained with monoclonal antibodies that had been raised to cultured cell lines and specifically teach that cultured tumor cells may not be antigenically typical of the tumor cell population from which they were derived and it is well

established that new artifactual antigens can occur as a result of culture (see attached abstract). Additionally Clark et al. (US Pat. App. Pub. 2006/0019256, January 2006) teach that “[a]lthough cell lines have led to remarkable advances in our understanding of the molecular and biochemical changes in cancer cells, their use in the identification of effective cancer therapies is somewhat limited. Cell lines are imperfect predictors of drug efficacy in *de novo* tumors. Several factors likely account for this deficiency. Cancer cell lines are selected from a sub-population of cancer cells that are specifically adapted to growth in tissue culture and the biological and functional properties of these cell lines can change dramatically. Furthermore, cancer cells from only a minority of breast cancer tumors establish cell lines or xenograft tumors. The phenotypic and functional characteristics of these cell lines can change drastically relative to their properties *in vivo*. For example, the marker expression of both normal hematopoietic and leukemic tissue culture cells can change rapidly in tissue culture and often does not reflect that of the original stem cells from which they were derived . . . Taken together, these observations suggest that the biological properties of cell lines can differ markedly from the cancer cells from which they were derived. This likely explains at least in part why the cell lines often are poor predictors of a drug's efficacy in the clinic,” see para. 0109.

Given that cultured cell lines do not predictably express the markers expressed by tumor cells *in vivo*, one of skill in the art would not predictably expect that all mixtures of proteomic cancer markers identified and not yet identified from different types of cancer cells would be useful for the generation of polyclonal antibodies to form a reagent for cancer screening using saliva samples from patients. Given the above, one of skill in the art would not believe it more

likely than not that the claimed invention would function as claimed for the screening of cancer without undue experimentation.

The specification provides insufficient guidance with regard to these issues and provides insufficient working examples which would provide guidance to one skilled in the art and insufficient evidence has been provided which would allow one of skill in the art to predict that the invention will function as contemplated or claimed with a reasonable expectation of success. For the above reasons, it appears that undue experimentation would be required to practice the claimed invention.

7. Claims 1-3, 8-12, 16-18, 20 and 24 are rejected as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to using a mixture from different types of cancer cells containing proteomic cancer markers identified and markers not yet identified or a mixture of proteomic cancer obtained from breast, liver, colon, and ovarian cancers, said mixture containing proteomic cancer markers identified and markers not yet identified. The claims lack any limitation on said mixtures containing proteomic cancer markers identified and markers not yet identified. When given the broadest reasonable interpretation, the terms "a mixture from different types of cancer cells containing proteomic cancer markers identified and markers not yet identified or a mixture of proteomic cancer obtained from breast, liver, colon, and ovarian cancers, said mixture containing proteomic cancer markers identified and markers not yet identified" encompasses numerous combinations of numerous types of cancer cells containing

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multiple cellular component such as a protein, nucleic acid, lipids, ions, other small intracellular molecules, a carbohydrate or polysaccharide, thus the genus of mixtures is highly variant which vary significantly both in structure and function from each other. The description of a mixture of markers from the HT-29/breast cancer, Diji/colon cancer, CCL-13/liver, and Sk-ov-3/ovarian cancer cells fails to adequately describe the genus of mixtures because said genus tolerates members which differ significantly in both structure and function from the mixture of markers from the HT-29/breast cancer, Diji/colon cancer, CCL-13/liver, and Sk-ov-3/ovarian cancer cells. One of skill in the art can reasonably conclude that applicant was not in possession of a genus of "a mixture from different types of cancer cells containing proteomic cancer markers identified and markers not yet identified" at the time the invention was filed. Because the genus of a mixture from different types of cancer cells containing proteomic cancer markers identified and markers not yet identified is not adequately described, the method claims relating to said genus are also not adequately described.

Although drawn to DNA arts, the findings in *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997) and *Enzo Biochem, Inc. v. Gen-Probe Inc.* are relevant to the instant claims. The Federal Circuit addressed the application of the written description requirement to DNA-related inventions in *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997). The court stated that "[a] written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *Id.* At 1567, 43 USPQ2d at 1405. The court also stated that a generic statement such as "vertebrate insulin cDNA" or

"mammalian insulin cDNA" without more, is not an adequate written description of the genus because it does not distinguish the genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. *Id.* At 1568, 43 USPQ2d at 1406. The court concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." *Id.*

In the instant case the genus is only described as a definition by function (i.e the ability to form polyclonal antibodies), and beyond that example of a mixture of markers from the HT-29/breast cancer, Diji/colon cancer, CCL-13/liver, and Sk-ov-3/ ovarian cancer cells, one of skill in the art cannot readily visualize or recognize the identity of members of the genus.

8. Claims 1-3, 8-12, 16-18, 20 and 24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The limitations of "a mixture from different types of cancer cells containing proteomic cancer markers identified and markers not yet identified or a mixture of proteomic cancer obtained from breast, liver, colon, and ovarian cancers, said mixture containing proteomic cancer

markers identified and markers not yet identified” in claims 1 and 16 have no clear support in the specification and the claims as originally filed. In the remarks of November 26, 2007 in regards to the base claims 1 and 16, Applicants state that support for the limitation "a plurality of proteomic cancer markers" is found in original claim 15, for example, which recites "antibodies made against a plurality of proteomic cancer markers". Fair support for the limitation "said mixture containing markers identified and markers not yet identified" is found in the specification at page 7, lines 25-26, which reads: "Each type of cancer cell has its own identified and not yet identified cancer markers." In the remarks of January 31, 2008 Applicants state that Claim 16 has been amended to recite: "providing a mixture of proteomic cancer markers obtained from breast, liver, colon, and ovarian cancers." The limitation is fairly supported by page 9, line 21, which reads: "*Mix PCM consisted of mixture of PCMs for breast, colon, liver and ovary".

A review of the specification discloses support for "antibodies made against a plurality of proteomic cancer markers" (claim 15), "Each type of cancer cell has its own identified and not yet identified cancer markers." (page 7, lines 25-26), and "*Mix PCM consisted of mixture of PCMs for breast, colon, liver and ovary" (page 9, line 21). The suggested support is not found persuasive because there is nothing in the specification to suggest the broadly claimed mixture of proteomic markers from different types of cancer cells or breast, liver, colon, and ovarian cancers, which includes cells directly obtained from tumors in addition to markers from cancer cell lines. The subject matter claimed in claims 1-3, 8-12, 16-18, 20 and 24 broadens the scope of the invention as originally disclosed in the specification.

9. All other objections and rejections recited in the Office Action of August 23, 2007 are withdrawn.

10. No claims allowed.

11. This action is a **final rejection** and is intended to close the prosecution of this application. Applicant's reply under 37 CFR 1.113 to this action is limited either to an appeal to the Board of Patent Appeals and Interferences or to an amendment complying with the requirements set forth below.

If applicant should desire to appeal any rejection made by the examiner, a Notice of Appeal must be filed within the period for reply identifying the rejected claim or claims appealed. The Notice of Appeal must be accompanied by the required appeal fee.

If applicant should desire to file an amendment, entry of a proposed amendment after final rejection cannot be made as a matter of right unless it merely cancels claims or complies with a formal requirement made earlier. Amendments touching the merits of the application which otherwise might not be proper may be admitted upon a showing a good and sufficient reasons why they are necessary and why they were not presented earlier.

A reply under 37 CFR 1.113 to a final rejection must include the appeal form, or cancellation of, each rejected claim. The filing of an amendment after final rejection, whether or not it is entered, does not stop the running of the statutory period for reply to the final rejection unless the examiner holds the claims to be in condition for allowance. Accordingly, if a Notice of Appeal has not been filed properly within the period for reply, or any extension of this period obtained under either 37 CFR 1.136(a) or (b), the application will become abandoned.

12. Applicants' amendments necessitated the new grounds of rejection. Thus, **THIS ACTION IS MADE FINAL**. Applicant is reminded of the extension of time policy as set forth in 37 C.F.R., 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R., 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

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13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter J. Reddig whose telephone number is (571) 272-9031. The examiner can normally be reached on M-F 8:30 a.m.-5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Peter J Reddig/

Examiner, Art Unit 1642

/P. J. R./

/Karen A Canella/

Primary Examiner, Art Unit 1643